

10091474

510(K) Summary, K09

JUL - 9 2009

Masters Healthcare, LLC  
11930 Kemper Springs Drive,  
Cincinnati, Ohio 45240, U.S.A.  
Ph: 513 619-8030  
Fax: 513 354-2687  
Contact person: John Edmiston  
Date prepared: May 14, 2009

1. Trade Name: Easy•Touch Insulin Syringe  
Common Name: Insulin syringe  
Classification Name: Syringe, piston, product code FMF, Regulation: 880.5860  
Class of device: Class II.
2. The legally marketed device to which we are claiming equivalence [807.92(a)(3)] :  
Feel-ject Insulin Syringe made by Feel Tech (Korea) K070917
3. Description of device: The Easy•Touch insulin syringe consists of a calibrated hollow barrel which can contain the medication and the distal end of barrel is fixed with needle . The needle cannot be exchanged after assembling because needle is fixed in the barrel nozzle lumen. The plunger and gasket are the same shape as the conventional insulin syringes. The needle cap cover is intended to provide physical protection to the needle tube. The cap is color coded orange, same as equivalent insulin syringes. The syringes are available in 0.3 ml/cc, 0.5 ml/cc and 1 ml/cc sizes. They are supplied with a sterile fluid path, (EO), non-toxic, and non pyrogenic, for single use only, disposable. The devices operate on the principles of common piston syringes.
4. Intended use: For the injection of U100 insulin.
5. Technological characteristics: The Easy•Touch Insulin Syringes and the predicate devices have identical technological characteristics and perform the same way as common piston syringes. These syringes are EO sterilized.
6. Performance: Bench tests were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues. The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Masters Healthcare, LLC  
C/O Mr. Daniel Kamm  
Principal Consultant  
Kamm & Associates  
333 Milford Road  
Deerfield, Illinois 60015

JUL -9 2009

Re: K091474  
Trade/Device Name: Easy Touch Insulin Syringe  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: II  
Product Code: FMF  
Dated: May 15, 2009  
Received: May 29, 2009

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

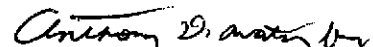
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
Susan Runner, D.D.S., M.A.

Acting Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: Easy•Touch Insulin Syringe

Indications For Use:

The Easy•Touch disposable sterile insulin syringes are intended for injection of U100 insulin only.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

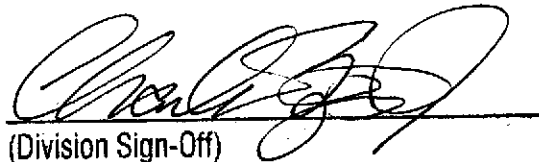
AND/OR

Over-The-Counter Use X \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K091474